Applicant: Patrice Flaherty
Application No: 10/630,402
Filing Date: 07/30/2003
Attorney Docket No: 1066

REMARKS

Claims 1-32 are pending herein.

Claims 12-23 are withdrawn from consideration.

Claims 1-11 and 24-32 are rejected.

Claims 1, 7 and 24 are currently amended.

Claim Objections

Claim 32 was objected to because the positive recitation of "a port tubing bifurcation" is structurally unclear. Appropriate correction was required.

It is respectfully submitted that claim 32 recites, "The device of claim 1 further comprising a tubing bifurcation [reference numeral 5 in Fig. 1 of the drawings] having a syringe leg [5a] and a collector tubing leg [5b] communicating with said main tubing segment [2] and wherein said syringe port [10] communicates with said syringe leg [5a] and said indicator unit 18] communicates with said collector tubing leg [5b]".

It is respectfully submitted that claim 32 as presently worded does not recite "a port tubing bifurcation". It is further respectfully submitted that claim 32 is structurally clear based on a consideration of Fig. 1 of applicant's drawings and applicant's specification. Reconsideration and removal of the objection to claim 32 is therefore respectfully solicited.

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Claim rejections under 35 U.S.C. 102

Claims 7-11 were rejected under 35 U.S.C. 102(b) as being anticipated by Strittmatter (U.S. Pat. No. 5,396,899).

It is respectfully submitted that Strittmatter fails to disclose a device comprising "a main tubing segment...an indicator unit and a syringe port *disposed in fluid communication with said main tubing segment...*", as set forth in amended claim 7 and defined by claims 8-11 as dependent therefrom.

In contrast, in the Strittmatter device, a seal (15) provides fluid separation between the spinal puncture needle (11) and the hub seat (24). As indicated in col. 3, lines 8-12, the purpose of the seal (15) is to "prevent fluid flow through the stylet port". During use of the Strittmatter device, a solid stylet (16) remains inserted through the seal (15), as shown in Fig. 2, to prevent fluid flow through the stylet port (col. 5, lines 58-61) and confine the fluid flow path to the flexible tube (21) and sample container (30). Therefore, the hub seat (24) is not "disposed in fluid communication with" the spinal puncture needle (11).

It is further respectfully submitted that Strittmatter fails to disclose a device comprising "a main tubing segment... a clamp *operably engaging said main tubing segment* for *selectively blocking said main tubing segment...*", as set forth in amended claim 7 and defined by claims 8-11 as dependent therefrom.

A close review of Strittmatter fails to disclose a clamp which "operably

engages" the spinal puncture needle (11) to selectively block and unblock the main tubing segment. In contrast, as shown in Fig. 2 of Strittmatter, a valve (20) is provided inside the tubing segment (21) to facilitate selective flow of fluid from the tubing segment (21) to either a filter (22) or a connector (19) which leads to a sample container (25).

It is further respectfully submitted that Strittmatter fails to disclose a device comprising "a main tubing segment...an indicator unit and a syringe port disposed in fluid communication with said main tubing segment...*said indicator unit and said syringe port defining branched bidirectional fluid flow pathways*...", as set forth in amended claim 7 and defined by claims 8-11 as dependent therefrom.

As was set forth herein above, the seal (15) in the junction member (12) of the Strittmatter device blocks fluid communication between the spinal puncture needle (11) and the hub seat (24) even when the solid stylus (16) remains inserted through the seal (15) during use of the device, as shown in Fig. 2 of Strittmatter. Therefore, as further shown in Fig. 2 of Strittmatter, the unbranched fluid flow path is confined to the spinal puncture needle (11), the junction member (12), the tubing segment (21) and the sample container (25). Accordingly, the hub seat (24) does not define a fluid flow pathway. Furthermore, the membrane (34) in the Strittmatter device is adapted for unidirectional, rather than bidirectional, flow of fluid as indicated by the arrows in Fig. 2 of Strittmatter.

It is further respectfully submitted that Strittmatter fails to disclose a device comprising "a main tubing segment...an indicator unit and a syringe port disposed in fluid communication with said main tubing segment...*said indicator unit and said syringe port defining branched bidirectional fluid flow pathways*...at least one air-permeable and liquid-impermeable membrane provided in said indicator unit *and allowing bidirectional fluid movement between said indicator unit and said syringe port*", as set forth in claim 7 and defined by claims 8-11 as dependent therefrom.

In contrast, as shown in Fig. 7 of Strittmatter, the membrane (34) in the sample container (30) of the Strittmatter device facilitates one-way flow of air from the sample container (30) through the opening (33). Furthremore, the hub seat (34) does not define a fluid flow pathway due to the presence of the seal (15) in the junction member (12), as was set forth herein above.

Therefore, it is respectfully submitted that Strittmatter fails to anticipate claim 7, and claims 8-11 as dependent therefrom, under 35 U.S.C. 102(b). Reconsideration and allowance of claims 7-11 is respectfully solicited.

Claim rejections under 35 U.S.C. 103

Claims 1-6 and 24-32 were rejected under 35 U.S.C. 103(a) as being unpatentable over Strittmatter in view of Prager (U.S. Pat. No. 4,257,416).

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It is respectfully submitted that Strittmatter in view of Prager fails to render claims 1-6 and 24-32 obvious under 35 U.S.C. 103(a), as set forth herein below.

Strittmater in view of Prager fails to teach invention of claims 1-6

It is respectfully submitted that Strittmatter in view of Prager fails to teach or suggest a device comprising "a main tubing segment...an indicator unit and a syringe port *disposed in fluid communication with said main tubing segment...*", as set forth in amended claim 1 and defined by claims 2-6 as dependent therefrom.

In contrast, as shown in Fig. 2, Strittmatter teaches placement of a seal (15) between the spinal puncture needle (11) and the hub seat (24) of the Strittmatter device to "prevent fluid flow through the stylet port of the device". Strittmatter further teaches insertion of a solid stylet (16) through the seal (15) during use of the Strittmatter device, as further shown in Fig. 2, to "prevent fluid flow through the stylet port" (col. 3, lines 11 and 12) and confine the fluid flow path to the spinal puncture needle (11), the junction member (12), the flexible tube (21) and the sample container (30) of the device during use.

It is respectfully submitted that Prager would fail to provide any teaching, suggestion or motivation to a person of ordinary skill in the art to modify the Strittmatter device in such a manner that the hub seat (24) is disposed in fluid communication with the spinal puncture needle (11) of the Strittmatter device.

Such a modification would cause undesired leakage of cerebrospinal fluid from the hub seat (24) rather than confining the fluid flow pathway of cerebrospinal fluid to the tubing segment (21) and sample container (30).

Therefore, it is respectfully submitted that Strittmatter in view of Prager fails to render claims 1-6 obvious under 35 U.S.C. 103(a). Reconsideration and allowance of claims 1-6 is therefore respectfully solicited.

Strittmater in view of Prager fails to teach invention of claims 24-32

It is respectfully submitted that Strittmatter in view of Prager fails to teach or suggest a device comprising "a main tubing segment...an indicator unit and a port *disposed in fluid communication with said main tubing* segment...", as set forth in claim 24 and defined by claims 25-32 as dependent therefrom, for the same reasons as were set forth herein above with respect to the rejection of claims 1-6.

It is further respectfully submitted that Strittmatter in view of Prager fails to teach or suggest a device comprising "a main tubing segment...an indicator unit and a port disposed in fluid communication with said main tubing segment...*said indicator unit and said port defining branched fluid flow pathways*...", as set forth in amended claim 24 and defined by claims 25-32 as dependent therefrom.

In contrast, Strittmatter teaches placement of a seal (15) in the junction member (12) of the Strittmatter device to block fluid communication between the

spinal puncture needle (11) and the hub seat (24) even when a solid stylus (16) remains inserted through the seal (15) during use of the device, as shown in Fig. 2 of Strittmatter. The purpose of the seal (15) is to confine the fluid flow path to the spinal puncture needle (11), the junction member (12), the tubing segment (21) and the sample container (25) of the device.

It is respectfully submitted that Prager would fail to provide any teaching, suggestion or motivation to a person of ordinary skill in the art to modify the Strittmatter device in such a manner that the hub seat (24) and the sample container (25) define "branched fluid flow pathways" of the Strittmatter device. Such a modification would cause undesired leakage of cerebrospinal fluid from the hub seat (24) rather than confining the fluid flow pathway of cerebrospinal fluid to the tubing segment (21) and sample container (30).

Furthermore, it is respectfully submitted that Strittmatter in view of Prager fails to teach or suggest a device comprising "a main tubing segment... a clamp operably engaging said main tubing segment and adapted to *crimp and selectively block and unblock said main tubing segment*...", as set forth in amended claim 24 and defined by claims 25-32 as dependent from amended claim 24.

In contrast, Strittmatter teaches a three-way valve (20) which operably engages a tubing segment (21) of the Strittmatter device to facilitate selective flow of fluid from the tubing segment (21) to either a filter (22) or a connector (19) which

leads to a sample container (25). The three-way valve (20) is provided inside the tubing segment (21) and is rotated therein to selectively establish fluid communication between the spinal puncture needle (11) and a selected one of the filter (22) and the sample container (30).

It is respectfully submitted that Prager would fail to provide any teaching, suggestion or motivation to a person of ordinary skill in the art to modify the Strittmatter device in such a manner that a clamp is provided on the spinal puncture needle (11) and is adapted to "crimp" the spinal puncture needle (11) in order to "selectively block and unblock" the spinal puncture needle (11).

It is further respectfully submitted that Strittmatter in view of Prager fails to teach or suggest a device comprising "a main tubing segment...an indicator unit and a port disposed in fluid communication with said main tubing segment...*said indicator unit and said port defining branched fluid flow pathways...wherein said at least one air-permeable membrane allows bidirectional fluid movement between and through said indicator unit and said syringe port*", as set forth in amended claim 24 and defined by claims 25-32 as dependent therefrom.

In contrast, as shown in Fig. 7 of Strittmatter, the membrane (34) in the sample container (30) of the Strittmatter device facilitates one-way flow of air from the sample container (30) through the opening (33). Strittmatter fails to teach or suggest operation of the Strittmatter device in such a manner that the membrane (34)

facilitates "bidirectional fluid movement between and through" the sample container (30) and the hub seat (24). As was set forth herein above, the hub seat (24) does not define a fluid flow pathway due to the presence of the seal (15) in the junction member (12).

It is respectfully submitted that Prager would fail to provide any teaching, suggestion or motivation to a person of ordinary skill in the art to modify the Strittmatter device in such a manner that the membrane (34) of the Strittmatter device facilitates "bidirectional fluid movement between and through" the sample container (30) and the hub seat (24) of the device.

Therefore, it is respectfully submitted that Strittmatter in view of Prager fails to render claims 24-32 obvious under 35 U.S.C. 103(a). Reconsideration and allowance of claims 24-32 is therefore respectfully solicited.

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Conclusion

Every effort has been made to amend applicant's claims in order to define the invention in the scope to which it is entitled. Accordingly, reconsideration and allowance of claims 1-11 and 24-32 is respectfully solicited.

Respectfully submitted,

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